REMARKS

STATUS OF THE CLAIMS

Claims 4-17 were pending, claims 1-3 having been previously canceled. Claims 16 and 17 have been cancelled without prejudice. Claims 4-7 are withdrawn as being drawn to a non-elected invention, e.g., method claims. Claims 9, 10, 14 and 15 have been withdrawn as drawn to non-elected sequences. Claims 4, 7-11, and 14 have been amended herein. Following entry of the amendments claims 8 and 11-13 will be pending and at issue.

SUPPORT FOR THE AMENDMENTS TO THE CLAIMS

Withdrawn method claim 4 has been amended to more clearly depend on composition claim 8, incorporating the limitations of amended claim 8. Withdrawn method claim 7, dependent on claim 4, has been amended to more clearly recite the identification of the probes used in the method.

Claims 11 and 14 have been amended to change "12 to 50 nucleotides in length" to "19 to 32 nucleotides in length." Support can be found throughout the specification as filed, e.g., the sequence listing (SEQ ID NO:15 (32 nucleotides in length) and SEQ ID NO:19 (19 nucleotides in length).

Claims 8-11 and 14 have been amended to merely change "a full length complement" to "the complement" in response to the Examiner's suggestions.

The amendments to the claims therefore add no new matter and entry is respectfully requested.

SUPPORT FOR AMENDMENTS TO THE SPECIFICATION

The specification has been amended at paragraph [00011] to delete reference to an embedded hyperlink. The Abstract was amended to merely delete the language "Described herein."

The amendments therefore add no new matter and entry is respectfully requested.

IDS

Applicant notes with appreciation the Examiner's thorough consideration of the references cited in the IDS (Form PTO/SB/08b).

STATEMENT OF SUBSTANCE OF INTERVIEW

Applicant thanks the Examiner for her time during a telephone interview on Tuesday February 27, 2007. Examiner Salmon, Examiner Carla Meyer, and Applicant's representative, Patent Agent Susan Hubl were present for the interview. No exhibits or demonstrations were presented or discussed. During the interview, all claims were discussed.

The Examiner indicated that substitution of the phrase "the complement" for the phrase "a full length complement" would overcome the indefiniteness rejection.

The Examiner indicated that overcoming the 103 rejection would require a clear showing of unexpected results for the recited nucleic acid sequences, e.g., SEQ ID NO: 4 and SEQ ID NO: 8.

ELECTION/RESTRICTION REQUIREMENT

In the Office Communication dated August 4, 2006, the Examiner stated that for the elected claims (Claims 8-17) the composition of a first polynucleotide (SEQ ID NO:4) and second polynucleotide (SEQ ID NO:8) would be searched and requested that a specific probe set be selected. In response, Applicant elected a primer/probe set of oligonucleotides wherein said set consists of forward primers and reverse primers and hybridization probes, wherein each oligonucleotide consists of one of SEQ ID NOS: 1, 2, 3, 5, 6, and 7.

In the Office Action October 27, 2006, the Examiner stated that "Claim 9 is withdrawn as being drawn to nonelected sequences." Applicant respectfully points out that claim 9 is drawn to the elected sequences SEQ ID NO:4 and SEQ ID NO:8, with the addition of at least one sequence selected from the group consisting of SEQ ID NOS: 12, 16, 20, and 24. Claim 10, dependent on claim 9, is drawn to all 6 sequences; dependent claims 14 and 15 are drawn to oligonucleotides specific to the sequences. Accordingly, Applicant believes that a search for

both SEQ ID NO:4 and SEQ ID NO:8 will turn up any art applicable to claims 9, 10, 14, and 15 and these claims do not need to be withdrawn.

However, to further prosecution Applicant has withdrawn claims 9-10 and 14-15. If claim 8 is allowed, these withdrawn composition claims should be rejoined.

In addition, Applicant notes that withdrawn method claims 4-7 should be rejoined if composition claim 8 is allowed.

OBJECTION TO THE ABSTRACT

The abstract of the disclosure was objected to because the abstract began with "Described herein." Applicant has amended the Abstract, and requests withdrawal of this objection.

OBJECTION TO THE SPECIFICATION

The disclosure was objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant has deleted the embedded hyperlink and/or other form of browser-executable code and withdrawal of the objection is requested.

The Examiner stated that "the specification does not provide any support for the length limitations in Claims 11, 14, and 16-17." Applicant respectfully disagrees. Paragraphs [0006] to [0008] clearly describe the claimed invention as including the SEQ ID NO: of the disclosed nucleotide sequences specific to Brucella and "any primers that are derived from these nucleotides sequences" or "any probes that are derived from these nucleotides sequences." It is well known to one of skill in the art that the derived primers and probes would have conventional lengths that are useful for the application, e.g., detection via a PCR assay, e.g., 12-50 nucleotides in length.

However, without agreeing with the Examiner's position but rather to further prosecution, Applicant has amended claims 11 and 14 to recite "19 to 32 nucleotides in length." Support can be found in the specification as filed, SEQ ID NO:15 (32 nucleotides in length) and SEQ ID NO:19 (19 nucleotides in length). Applicant requests withdrawal of this objection.

OBJECTION TO THE CLAIMS

Claim 10 was objected to because of depending on Claim 9, withdrawn by the Examiner. Applicant has withdrawn Claim 9 herein, rendering moot this objection.

REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 8 and 10-17 were rejected as allegedly indefinite over the recitation of "full length complement." Applicant has amended the claims to recite the Examiner's suggested "the complement" and requests withdrawal of this rejection.

REJECTIONS UNDER 35 U.S.C. § 103

Claims 8 and 10 were rejected under 35 U.S.C. 103(a) as allegedly unpatentable over GenBank Accession Number AE008917 (December 28, 2001) in view of DelVecchio et al. (PNAS January 8, 2002 Vol. 99 p. 443). Applicant respectfully disagrees.

The Examiner stated that

> Genbank Accession Number AE008917 teaches the complete sequence of the genomic DNA isolated by DelVecchio et al. Nucleotides 1347-1164 are a 100% match to SEQ ID No. 4. Nucleotides 1710-1515 are a 100% match to SEQ ID Number 8.
>
> Genbank Accession Number AE008917, however, does not teach a composition comprising a first and second isolated polynucleotide consisting of SEQ ID No. 4 or a full-length complement and SEQ ID No. 8 or a full length complement.
>
> With regard to Claim 8 and 10, DelVecchio et al. teaches B. melitensis strain 16M high molecular weight genomic DNA was isolated was sheared, size fractionated and used to construct libraries (p. 443 2nd column 1st full paragraph). Therefore DelVecchio et al. teaches a composition (sheared DNA in a library) in which various fragments of the B. melitensis sequence is contained. DelVecchio et al. teaches the sequences from the library were combined to assemble a genome, which was deposited as GenBank Accession Numbers AE008917 and AE008918 (p. 443 2nd column 1st full paragraph and foot note).
>
> Therefore it would have been prime facie obvious to one of ordinary skill in the art at the time the invention was made that the high molecular weight genomic DNA which was sequenced in DelVecchio et al. is the nucleotides of GenBank Accession Number AE008917. It would have been obvious to the ordinary artisan that the nucleotides presented in GenBank Accession Number AE008917 are the nucleotides which were sequenced by shear fractionation by DelVecchio et al. because DelVecchio et al. teaches the sequences were deposited as GenBank

> Accession Numbers AE008917 and AE008918 (p. 443 2nd column 1st full paragraph and foot note).

Applicant's invention is a species that is not rendered obvious by the genus taught by the prior art

The Examiner is arguably describing a genus (any number of fragments of undefined length and sequence of the Brucella genome) to improperly render obvious the species that is Applicant's claimed invention, e.g., SEQ ID NO:4 and SEQ ID NO:8. In *In re Baird* the Federal Circuit stated that "The fact that a claimed compound may be encompassed by (prior) disclosed generic formula does not by itself render that compound obvious". In the instant case, the fact that SEQ ID NO:4 and SEQ ID NO:8 may be encompassed by a combination of art disclosing any number of fragments of undefined length and sequence of the Brucella genome does not by itself render SEQ ID NO:4 and SEQ ID NO:8 obvious.

The obviousness argument can be rebutted using evidence that the claimed invention possesses unexpected properties.

In contrast to the properties of any fragment of undefined length and sequence from the Brucella genome, polynucleotides consisting of SEQ ID NO:4 and SEQ ID NO:8 of the instant invention have the unexpected property of being useful for detection of Brucella melintensis in a sample with no false positives and no false negatives.

Problems with prior methods for detection of Brucella in a sample were described in the specification:

> [00013] Existing detection methods have resulted in a higher than acceptable rate of false positive and false negative results. Such results are inadequate and can create confusion regarding the appropriate countermeasures, if any, that should be undertaken because it is unclear whether the bacterium is present or not. If the bacterium is not present, undertaking counter measures may cause undue expense and create unwarranted concern among those that may incorrectly believe they have been exposed.

[00014] Although the genome for Brucella has already been mapped, this alone was not sufficient to develop a reliable and accurate detection mechanism because the current methods use nucleotide sequences that may be common to many different bacteria. Thus, existing detection methods could not distinguish between various bacteria, which resulted in higher than acceptable false positive detection rates. Similarly, some existing detection methods resulted in false negative results because they were not sensitive enough to detect the bacterium.

In addition, problems with detection of Brucella using either non-PCR or PCR based methods are described in numerous publications including art cited in the IDS, e.g., Casana et al (2001); Rijpens et al (1996); and (Zerva et al (2001), see introductions. Earlier methods used sequences common to many different bacteria and had problems with both false positives and false negatives.

In contrast to the problems described in the art, Applicant's claimed polynucleotides consisting of SEQ ID NO:4 and SEQ ID NO:8 can be used for detection of Brucella melintensis with no false negatives and no false positives. This is demonstrated in the Examples section of the specification. The described experiment showed that detection of Brucella melintensis DNA was successfully accomplished using detection of polynucleotides consisting of SEQ ID NO:4 and SEQ ID NO:8. In contrast, polynucleotides consisting of SEQ ID NO:4 and SEQ ID NO:8 could not be detected in environmental soil samples, demonstrating that false positives are not obtained using Applicant's invention.

In conclusion, polynucleotides consisting of SEQ ID NO:4 and SEQ ID NO:8 have the unexpected property of being useful for detection of Brucella melintensis with no false positives of false negatives. Therefore, a prima facie case of obviousness is not made. Withdrawal of this ground of rejection is respectfully requested.

CONCLUSION

Consideration of the claims is respectfully requested, and a notice of allowance is earnestly solicited. If the Examiner has any questions concerning this Response, the Examiner is invited to telephone Applicant's representative at (415) 875-2316.

Respectfully submitted,
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